indication that the prospective cosmetology school student is similar to the typical vocational school student. As the Commission noted in promulgating the Rule, "[b]ecause the typical student is young, has limited educational and work experience, and is either unemployed or earning a low salary, he or she is likely to be more susceptible than the general adult population to unfair sales practices." [10] Petitioner has made no showing that prospective cosmetology school students are less vulnerable than other vocational school students, that the retention rates of cosmetology schools differ from that for the rest of the vocational school industry, or that cosmetology schools are providing material information regarding drop-out rates, or placement rates when job or earnings claims are made.

Invitation To Comment on Requested Exemption

Upon consideration of the petition of the National Association of Cosmetology Schools, the Commission has decided that more information is needed to determine whether an exemption should be granted and the extent of such exemption. The Commission, therefore, seeks comment regarding the exemption requested by NACS.

All interested parties are hereby notified that they may submit written data, views or argument on any issues of fact, law or policy that may have some bearing on the requested exemption. Such submissions may be made for sixty days to the Secretary of the Commission.

The Commission requests that persons commenting on the proposal address the following issues in particular:

1. To what exent do cosmetology schools make representations to prospective students regarding course content, ability of students to succeed, value of course, placement opportunities, or job demand? What evidence is there concerning possible misrepresentations?

2. To what extent do cosmetology schools fail to disclose information regarding graduates and drop-out rates of their students?

3. To what extent do cosmetolgoy school representatives utilize pressure sales tactics to induce students or prospective students to sign enrollment contracts?

4. To what extent do cosmetology school representatives engage in other unfair acts or practices, including practices which circumvent currently applicable cooling-off requirements?

5. What will be the impact on schools if the exemption is not granted?

6. What will be the impact on students if the exemption is granted? If it is not granted?

7. What has been the effect of state pro rata requirements on cosmetology schools?

8. Do all cosmetology schools use the "double source of income" structure?

9. Does this fee structure create incentives to prevent unfair or deceptive practices comparable to those provided by the pro rata refund provision? The cooling-off provision?

10. (a) If an exemption from the pro rata refund requirements is deemed proper, should it apply only to cosmetology schools actually using the "double source of income" method?

(b) If the Commission concludes that an exemption is warranted and should be given only where the "double source of income" structure exists, what portion of the income derived from a course should be attributable to the services of students enrolled in that course in order to trigger the exemption?

(c) How should the ratio of income attributable to tuition versus student services be calculated?

11. Should a modified version of the pro rata refund provision apply to cosmetology schools if a complete exemption from that provision is not warranted? If so, how should the provision be modified?

12. How should cosmetology schools be defined for purposes of an exemption? [11]

13. Should cosmetology schools be treated as a "class" or are there distinguishing characteristics among such schools that make such treatment inappropriate?

Written comments will be accepted until September 11, 1979. Comments may be filed in person or mailed to:

Secretary, Federal Trade Commission, 6th & Pennsylvania Ave., N.W., Washington, D.C. 20580.

Comments should be identified as "Vocational School Exemption Comment" and, if possible, submitted in five copies. A copy of the Petition of the National Association of Cosmetology Schools is on file in Room 130 of the Federal Trade Commission at the above address.

By direction of the Commission.

Carol M. Thomas,

Secretary.

[FR Doc. 79-21756 Filed 7-12-79; 8:45 am]

BILLING CODE 6750-01-M

[10] Statement of Basis and Purpose, 43 FR 60798.

[11] Petitioner suggests the following definition:

"Any course that provides training for the occupations commonly known as cosmetologist, cosmetician, beauty operator, beautician, beauty culturist, hairdresser or other similar titles, which includes training for the care of hair, skin and nails, including but not limited to, treating hair by arranging, singeing, bleaching, coloring or otherwise whether by manual or mechanical or electrical means of treatment of the skin of the scalp, face, neck, arms or hands, by use of cosmetic preparations, lotions, creams, massage, manipulation, stimulation or otherwise; or manicuring or pedicuring the nails of any person."

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Public Information Meeting

Notice is hereby given pursuant to Section 800.6(b)(3) of the Council's regulations, "Protection of Historic and Cultural Properties" (36 CFR Part 800), that on July 20, 1979, at 7:30 p.m., a public information meeting will be held at the Agat Community Hall, Gaan Point, Guam. The meeting is being called by the Executive Director of the Council in accordance with Section 800.6(b)(3) of the Council's regulations. The purpose of the meeting is to provide an opportunity for representatives of national, State, and local units of government, representatives of public and private organizations, and interested citizens to receive information and express their views concerning the small boat harbor proposed to be built by the Corps of Engineers at Gaan Point, Guam. The project will adversely affect the Agat Invasion Beach, a property included in the National Register of Historic Places, and a unit of the War in the Pacific National Historical Park. Consideration will be given to the undertaking, its effects on National Register properties, and alternate courses of action that could avoid, mitigate, or minimize any adverse effects on such properties.

The following is a summary of the agenda of the meeting.

I. An explanation of the procedures and purposes of the meeting by a representative of the Executive Director of the Council.

II. A description of the undertaking and an evaluation of its effects on the property by the Corps of Engineers.

III. A statement by the Guam Historic Preservation Officer.

IV. Statement from local officials, private organizations, and the public on the effects of the undertaking on the property.

V. A general question period.

Speakers should limit their statements to 5 minutes. Written statements in furtherance of oral remarks will be accepted by the Council at the time of the meeting. Additional information regarding the meeting is available from the Executive Director, Advisory

Council on Historic Preservation, 1522 K Street NW., Washington, D.C. 20005, 202–254–3974.

Robert R. Garvey, Jr.,

Executive Director.

[FR Doc. 79–21472 Filed 7–12–79; 8:45 am]

BILLING CODE 4310–10–M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 79P–0112]

Abbott Laboratories; Panel Recommendation on Petition for Reclassification

Correction

In FR Doc. 79–16991 appearing at page 31714 in the issue for Friday, June 1, 1979 make the following corrections:

(1) On page 31715 column one "Summary of Data on Which the Recommendation Is Based" paragraph 2, line 9, "PH4" should appear as "PF4".

(2) On page 31715 column two, paragraph 3, line 3 "PH4" should appear as "PF4".

(3) On page 31715 column two, paragraph 5, lines 9 and 14 "PH4" should appear as "PF4", and in line 13 "thrombeglobulin" should appear as "thromboglobulin".

BILLING CODE 1505–01–M

[Docket No. 79N–0198]

American Cyanamid Co.; Withdrawal of Approval of NADA for Cyzine Premix

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency withdraws approval of a new animal drug application (NADA) providing for use of Cyzine Premix 10% (containing 2-acetylamino-5-nitrothiazole) in turkey feed as an aid in prevention of blackhead. The sponsor, American Cyanamid Co., requested this action.

EFFECTIVE DATE: July 23, 1979.

FOR FURTHER INFORMATION CONTACT: David N. Scarr, Bureau of Veterinary Medicine (HFV–214), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3183.

SUPPLEMENTARY INFORMATION: American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, is sponsor of NADA 9–424 which provides for use of Cyzine Premix 10% in turkey feed as an aid in prevention of blackhead (histomoniasis). The application was originally approved July 21, 1954. By letter of February 16, 1979, the firm requested that approval of the NADA be withdrawn because the product is no longer being marketed.

Published elsewhere in this issue of the **Federal Register** is a final order revoking § 558.25 *2-Acetylamino-5-nitrothiazole* (21 CFR 558.25) to reflect withdrawal of approval of this application.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345–347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 9–424 and all supplements for Cyzine Premix 10% is hereby withdrawn, effective July 23, 1979.

Dated: July 6, 1979.

Terence Harvey,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79–21592 Filed 7–12–79; 8:45 am]

BILLING CODE 4110–03–M

[Docket No. 78F–0141]

Marshall Minerals, Inc.; Order Denying Petition for Food Additive Regulation on Gentian Violet; Extension of Time for Filing Data

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice extends the time for filing data to support a request for hearing on the order of denial of a petition proposing to establish a regulation to permit the safe use of gentian violet.

DATE: Data to be filed by August 3, 1979.

ADDRESS: Data to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Bureau of Veterinary Medicine (HFV–147), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4317.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is extending to August 3, 1979 the time for filing data to support a request for hearing on the order, published in the **Federal Register** of March 30, 1979 (44 FR 19035), on the denial of a petition proposing to establish a regulation to permit the safe use of gentian violet in animal feed.

The March 30, 1979 order gave interested persons until April 30, 1979 to file the data. Marshall Minerals, Inc., P.O. Box 506, Bainbridge, GA 31717, has requested additional time to respond to the subject order. Because of the amount of scientific material which must be reviewed and evaluated, FDA is granting the request.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1)(B), (e), (f), 72 Stat. 1786–1787 (21 U.S.C. 348(c)(1)(B), (e), (f)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), the time for filing data to support requests for a hearing on the subject order is extended to August 3, 1979.

Dated: July 6, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–21590 Filed 7–12–79; 8:45 am]

BILLING CODE 4110–03–M

[Docket No. 79N–0113; DESI 2847]

Parenteral Multivitamin Products: Drugs for Human Use; Drug Efficacy Study Implementation; Permission for Drugs To Remain on the Market

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration announces changes in the previously published conditions for marketing parenteral multiple vitamin preparations that have been allowed to remain on the market until appropriate formulations of such products could be agreed upon. The changes now being made require that manufacturers submit new drug applications (NDA's) or supplemental applications for reformulated products and test them in accordance with the criteria in this notice.

DATE: New drug applications (or supplemental new drug applications) must be submitted by October 11, 1979.

ADDRESSES: Responses to this notice should be identified with the NDA number (if any) and the following in a box in the upper portion of the cover letter: "Paragraph XIV Drug—Category XI (Parenteral Multivitamins)", directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

New drug applications (identify with NDA number): Documents and Records

Section (HFD–106), Rm. 8B–45, Bureau of Drugs.

Supplements to new drug applications (identify with NDA number): Division of Metabolism and Endocrine Drug Products (HFD–130), Rm. 14B–04, Bureau of Drugs.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD–310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD–501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT: Walid Y. Ibrahim, Bureau of Drugs (HFD–130), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3520.

SUPPLEMENTARY INFORMATION: In a notice (DESI 2847) published in the **Federal Register** of July 27, 1972 (37 FR 15027), FDA announced its conclusion that, as currently formulated, parenteral multivitamin preparations lack substantial evidence of effectiveness for their claimed indications.

It is recognized that parenteral multivitamin therapy is essential in preventing or treating hypovitaminoses in certain disease states or postoperative conditions. The conclusion of lack of substantial evidence of effectiveness was not based upon lack of effectiveness of individual vitamins, but upon the finding that formulations now available lack certain essential vitamins, or contain too much or too little of other vitamins, or both. Because of the critical medical importance of parenteral multivitamin therapy and lack of alternative drugs, the Commissioner of Food and Drugs concluded that these products should remain available as presently formulated, to allow time to resolve the complex technical and medical problems and to develop and test rational formulations of parenteral multivitamin preparations. That conclusion was published in the **Federal Register** of December 14, 1972 (37 FR 26623). Formulations that are now believed to be rational ones and guidelines for their clinical study are now available. The notice that follows describes them in detail and specifies the conditions for continued marketing of presently marketed products while studies of appropriately reformulated products are in progress.

In the final report to the Commissioner on the Drug Efficacy Study by the National Academy of Sciences-National Research Council, Divison of Medical Sciences, the Panel on Drugs Used in Endocrine Disturbances and the Panel on Drugs Used in Metabolic Disorders stated as follows:

"The Panel does not recognize the need for multi-vitamin supplementation in healthy individuals who have an adequate diet. However, the Panel does recognize the need for multiple-vitamin and mineral preparations in certain segments of the population. It also recognizes the lack of precise data on which rational formulation can be based. Therefore, it takes the following position toward all such preparations:

"1. All should be appropriately labeled as either 'supplemental' or 'therapeutic.'

"2. The formulations of supplemental preparations should be based on dietary allowances recommended either by the Food and Nutrition Board of the National Academy of Sciences or by an equivalent body.

"3. Any preparations labeled 'therapeutic' should be so formulated that the physician can prescribe adequate therapeutic amounts without the danger of toxicity.

"4. The preparations should not contain disproportionate amounts of any nutrient that could be potentially hazardous in the recommended dosage. The recommended dosage and labeling for any fat-soluble vitamin should include proper warning concerning possible toxicity.

"5. The preparations should not contain non-essential materials.

"6. The Panel favors the use of oral preparations when it is feasible to use such formulations."

In October 1972, the American Medical Association (AMA) offered to assist FDA in determining rational formulations for parenteral multivitamins and in developing guidelines for studies concerning their stability, safety, and effectiveness. In December 1975, the AMA submitted its report entitled "Guidelines for Multivitamin Preparations for Parenteral Use." With certain minor exceptions, i.e., concerning the nomenclature for folic acid, the duration of clinical studies, and disease states in which clinical studies are required, FDA accepts the recommendations contained in the report. These exceptions are dealt with in the notice below. The report constitutes the scientific basis for this notice. The verbatim text of the report is on file with and may be seen in the office of the FDA Hearing Clerk, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. Single copies of the report are available from the Hearing Clerk at the above address.

The following parenteral multivitamin products were reviewed in the Drug Efficacy Study and were named in the notices of July 27, 1972, and December 14, 1972. These products and identical, similar, or related products, whether or not they are now the subject of an approved new drug application (NDA), may remain on the market as presently formulated, under the conditions specified below, pending completion of studies necessary to determine the stability, safety, and effectiveness of appropriately reformulated products. It is recognized that the composition of a product being allowed to continue on the market may differ substantially from the one being studied. However, this is necessary in order to assure that parenteral multivitamin products remain available to fulfill the critical medical need. Therefore, category XI, Parenteral Multivitamin Products, published in the notice of December 14, 1972, is amended to read as follows:

XI. Parenteral Multivitamin Products

1. NDA 4–895; Breonex L Injectable, and

2. Breonex M Injectable, both containing thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, panthenol, niacinamide, and cyanocobalamin; Cooper Laboratories, 1300 Fairfield Rd., Wayne, NJ 07470.

3. NDA 4–635; Beclysyl Injectable containing dextrose, sodium chloride, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, and cyanocobalamin; Abbott Laboratories, 14th and Sheridan Rd., North Chicago, IL 60064.

4. NDA 4–895; Parbexin Injectable containing thiamine hydrochloride, niacinamide, dexpanthenol, riboflavin, and pyridoxine hydrochloride; Smith, Miller & Patch, Division of Cooper Laboratories, P.O. Box 367, San German, Puerto Rico 00753.

5. NDA 6–071; Berocca-C Injectable, and

6. Berocca-C 500 Injectable, both containing thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, dexpanthenol, d-biotin, and ascorbic acid; Roche Laboraties, Division of Hoffmann-LaRoche, Inc., Roche Park, Nutley, NJ 07110.

7. NDA 6–141; Folbesyn Injectable containing thiamine hydrochloride, sodium panthothenate, niacinamide, riboflavin, pyridoxine, cyanocobalamin, ascorbic acid, and folic acid; Lederle Laboratories, Division of American Cyanamid Co., P.O. Box 500, Pearl River, NY 10965.

8. NDA 6–373; Vi-Syneral Injectable containing vitamin A, ergocalciferol, ascorbic acid, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, dexpanthenol, dl-alpha tocopherol acetate; USV Pharmaceuticals Corp., 1 Scarsdale Rd., Tuckahoe, NY 10707.

9. NDA 7–590; Manibee Injectable containing thiamine hydrochloride, niacinamide, dexpanthenol, pyridoxine hydrochloride, and riboflavin, and

10. Manibee-C 500 Injectable containing thiamine hydrochloride, niacinamide, dexpanthenol, pyridoxine hydrochloride, riboflavin, and ascorbic acid, Endo Laboratories, Inc., Subsidiary of E. I. duPont d

Nemours & Co., Inc., 1000 Stewart Ave., Garden City, NY 11530.

11. NDA 7-619; Betolake Improved Injectable containing thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, and dexpanthenol; Lakeside Laboratories, Inc., 1707 East North Ave., Milwaukee, WI 53201.

12. NDA 8-809; M.V.I. Injectable containing ascorbic acid, vitamin A, ergocalciferol, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, dexpnathenol, and dl-alpha tocopherol acetate; U.S.V. Pharmaceutical Corp.

13. NDA 7-094; Soluzyme Injectable containing cyanocobalamin, folic acid, thiamine hydrochloride, sodium pantothenate, and niacinamide; The Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49002.

The specific conditions for marketing parential multivitamin products are as follows:

A. Requirements for Products (as Presently Formulated) on the Market on July 13, 1979, Whether or Not Provided for in New Drug Applications

Proceedings to withdraw approval of NDA's (for presently formulated products) that have approved or "deemed approved" status on, July 13, 1979, or to take regulatory action to remove from the market products that are not subjects of approved or "deemed approved" new drug applications, will not be initiated provided that the following conditions are met:

1. On or before October 11, 1979, the manufacturer of any such product must submit a new drug application (NDA) (if currently marketed formulation is not now provided for in an NDA) or, if the currently marketed formulation is now the subject of an approved or "deemed approved" application, must supplement the NDA outlining the plan to fulfill these requirements. This plan must include: (a) the formulation(s) proposed for marketing, (b) the stability and biological availability studies proposed on this formulation(s), and (c) the general format of the clinical studies proposed on this formulation(s).

a. Product(s) must be formulated to be in accord with a formulation(s) recommended in the AMA report above except that the term "folacin" is replaced by the more specific nomenclature "floic acid."

b. Proposed studies of stability and biological availability of vitamins in the finished formulation must include those recommended in the AMA report above (Parts V, C and D). The amount of each vitamin added to provide, at the end of shelf life, a potency not less than 90 percent of that claimed on the label must not exceed 125 percent of the amount claimed on the label. Strict limitation of overage is necessary to ensure: (1) that the formulation does not contain potentially toxic amounts of any vitamin, the fat-soluble vitamins being of the most concern, and (2) that a physician can, with reasonable certainty, determine from the label the amount of each vitamin to be received by the patient at the beginning as well as the end of shelf life. If an applicant believes that the above overage limit is not feasible for one or more of the vitamins, then data documenting this should be submitted.

c. The plan for clinical studies proposed must be in accord with the guidelines set forth in the AMA report above. Although highly desirable, testing of the formulation(s) in patients from each of the categories listed in Table 5 of the AMA report is not required. However, at least two adequate and well-controlled clinical trials are required for each intravenous formulation, and the number of patients studied must be sufficient for clear demonstration of effectiveness.

Formulations to be marketed for adults must be tested in adults. Formulations to be marketed for children must be tested in both neonates and older children.

Determining the duration of a clinical study should take into account the duration of use reasonably expected in patients who will receive the formulation(s) when it is generally marketed.

Testing of a formulation for intramuscular administration that is indicated for brief clinical use may be limited to a clinical bioavailability study designed to demonstrate the equivalence of this formulation with a formulation for intravenous use, after clinical effectiveness and safety of the intravenous formulation have been studied.

Formulations for intravenous use should ideally be studied for the length of time necessary for depletion of body stores to the extent sufficient to produce decreasing blood/urine levels. Since such studies would be lengthy for some of the vitamins, such as vitamin B_{12} and the fat-soluble vitamins, they are not required. However, the formulation(s) may be the only source of vitamins for patients receiving total parenteral nutrition for many months or years. For this reason, studies of at least 4 months' duration and preferably of 6 months are required for at least one group of patients in this category: patients who require maintenance vitamins as part of long-term total parenteral nutrition.

Methodology in the field of vitamin assays in developing rapidly. If a manufacturer has reason to believe that an assay of: (1) a vitamin in a body fluid other than or in addition to the one(s) given in the AMA report, (2) a different assay method, or (3) a vitamin transport protein is a more accurate indicator of body stores, then this information should be submitted.

2. NDA's and supplements must be in organized form with sequential page numbers, a detailed table of contents referenced to the relevant pages, and tabulations, summaries, and discussion of the data. Otherwise they will be rejected.

3. The Bureau of Drugs will review submitted applications and approve or comment on the plan within 60 days. Within 60 days of receiving any comments from the Bureau, the applicant must respond; the Bureau will give final approval or disapproval of the plan within 60 days of this response. Plans disapproved at this step may be submitted in the usual manner as part of a Notice of Claimed Investigational exemption for a New Drug (IND) for the proposed product and will be handled under the usual IND/NDA procedures. Within 6 months after receipt of the Bureau's approval of the plan, the applicant must submit data on stability and biological availability, other relevant chemistry and manufacturing information, and detailed protocols for clinical studies in the form of an amendment to the NDA or NDA supplement. The Bureau will review and "conditionally approve" it if satisfactory. The product may then be marketed.

4. Within 90 days after receiving conditional approval, the applicant must begin the clinical trials discussed in 3(c) above, and must report the results of the trials to the Bureau of Drugs within one year after the date of conditional approval. The application will then be approved if satisfactory. Subsequent modifications of formulations on the basis of the results of clinical trials will be handled as supplements to approved NDA's.

5. Manufacturers of products containing the same ingredients at the same dosages or dosage ratios are encouraged to conduct studies in cooperation with one another and to submit joint protocols for clinical trials.

B. Requirements for Products Entering the Market After July 13, 1979.

Regulatory action will be taken against any such product that enters the market after July 13, 1979, that is not the subject of an approved or conditionally approved new drug application.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 505,

701, 52 Stat. 1052–1053, as amended 1055–1056, as amended, (21 U.S.C. 355, 371)) and the Administrative Procedure Act (5 U.S.C. 553, 554), and under authority delegated to the Commissioner (21 CFR 5.1).

Dated: July 6, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-21591 Filed 7-12-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 76N-0325; DESI 3265]

Certain Anticholinergic Drugs; Withdrawal of Approval of New Drug Applications

AGENCY: Food and Drug Administration (FDA).

ACTION: Notice.

SUMMARY: This notice withdraws approval of 15 anticholinergic drugs. The basis for the withdrawal is the election of the sponsors to neither contest the findings of the Food and Drug Administration that the drugs lack substantial evidence of effectiveness for certain indications, nor submit supplements showing (1) deletions of those indications from their labeling, and (2) updating of their new drug applications. The drug products are no longer marketed.

EFFECTIVE DATE: July 23, 1979.

ADDRESSES: Requests for an opinion of the applicability of this notice to specific drug product should be directed to the Division of Drug Labeling Compliance (HFD–310), Bureau of Drugs, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Carol A. Kimbrough, Bureau of Drugs (HFD–32), Food and drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3650.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 22, 1977 (42 FR 15468), FDA reclassified the probably and possibly effective indications of certain anticholinergic drugs to lacking substantial evidence of effectiveness and offered an opportunity for hearing concerning their reclassification. For those firms not requesting a hearing, but electing to retain their new drug application(s), the notice required the submission of (1) a supplement for labeling revised in accordance with the notice and (2) a supplement updating the new drug application. Approval of the following new drug applications, for which sponsors elected to neither request a hearing nor submit the requested supplements, is now being withdrawn:

NDA No.	Drug	NDA holder
3–265	Metropine Tablets, Hypodermic Tablets, Drops, Elixir and Injection, each containing methylatropine nitrate.	Pennwalt Prescription Product Division, P.O. Box 1766, Rochester, NY 14603.
8–398	Prantal Injection containing diphemanil methylsulfate	Schering Corp., Galloping Hill Rd., Kenilworth, NJ 07033.
8–492	That part pertaining to Antrenyl Bromide Pediatric Drops and Syrup, each containing oxyphenonium bromide.	Ciba Pharmaceutical Co., Division of Ciba-Geigy Corp., 556 Morris Ave., Summit, NJ 07901.
8–885	Centrine Tablets and Elixir, each containing aminopentamide sulfate.	Bristol Laboratories, Division of Bristol-Meyers Co., Box 657, Syracuse, NY 13201.
9–427	That part pertaining to Piptal Capsules and Elixir, each containing pipenzolate bromide.	Merrell National Laboratories, Division of Richardson-Merrell, Inc., 110 E. Amity Rd., Cincinnati, OH 45215.
9–262	Pamine Syrup containing methscopolamine bromide	The Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49002.
8–868	Elorine Chloride Pulvules containing tricyclamol chloride, and Elorine Sulfate Pulvules containing tricyclamol sulfate.	Eli Lilly & Co., P.O. Box 618, Indianapolis, IN 46206.
8–910	That part pertaining to Tricoloid Tablets containing tricyclamol chloride.	Burroughs Wellcome & Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709.
9–032	Monodral Bromide Caplets and Elixir, each containing penthienate bromide.	Winthrop Laboratories, Division of Sterling Drug Inc., 90 Park Ave., New York, NY 10016.
6–856	Dibulin Sulfate Injection containing dibutoline sulfate	Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, PA 19486.
11–687	That part pertaining to Tral Drops containing hexocyclium methylsulfate.	Abbott Laboratories, Abbott Park, 14th & Sheridan Rd., North Chicago, IL 60064.
9–801	Antrenyl Bromide Injection containing oxyphenonium bromide.	Ciba Pharmaceutical Co., Division of Ciba-Geigy Corp., 556 Morris Ave., Summit, NJ 07901.
10–281	Monodral Tablets containing penthienate bromide	Winthrop Laboratories, Inc., 90 Park Ave., New York, NY 10016.
8–494	Malcotran Tablets containing homatropine methylbromide.	Pennwalt Corp.
13–429	Valpin Elixir containing anisotropine methylbromide	Endo Laboratories, Inc., 1000 Stewart Ave., Garden City, NY 11533.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the applications reviewed and are subject to this notice under § 310.6 (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 following new drug application was also named in the notice of March 22, 1977.

NDA No.	Drug	NDA holder
9–489	That part pertaining to Pathilon Tablets and Pathilon Parenteral containing tridihexethyl chloride.	Lederle Laboratories, Div. of American Cyanamid Co., P.O. Box 500, Pearl River, NY 10965.

The sponsor of that new drug application submitted a request for hearing that FDA is now reviewing. Marketing of the drug products Pathilon Tablets and Pathilon Parenteral, for which the hearings request is under review, may continue pending a ruling on the request. (Several other hearing request were filed but later withdrawn by sponsors who then submitted revised labeling in accord with the requirement in the **Federal Register** notice of March 27, 1977.)

There are no other outstanding hearing requests filed in response to the March 22, 1977 notice. The failure to file such an appearance constitutes election not to avail oneself of the opportunity for a hearing.

The Director of the Bureau of Drugs, under the Federal Food, Drug, and Comestic Act, (sec. 505, 52 Stat. 1052–1053, as amended (21 U.S.C. 355)) and under authority delegated to him (21 CFR 5.82), finds that, on the basis of new information before him about each of these drug products, evaluated together with the evidence available to him when each application was approved, there is a lack of substantial evidence that each of the drugs will have the effect it purports or is represented to have under the conditions of use prescribed,