Syrup. FDA is also declaring all identical, similar, and related drug products, not otherwise subject to an approved drug application, unlawful, including Brofed Tablets and Hydroxyzine Compound Syrup. Each of these products contains theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. The basis of the withdrawals is that there is a lack of substantial evidence that these combination drugs are effective for the treatment of bronchial asthma.

EFFECTIVE DATE: August 7, 1998.

ADDRESSES: Requests for applicability of this notice to a specific product should be identified with the Docket and DESI numbers found in brackets in the heading of this document and directed to the Division of Prescription Drug Compliance and Surveillance (HFD–330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: As part of the agency's drug efficacy program, in a notice published in the **Federal Register** of September 17, 1984 (49 FR 36443), the Commissioner of Food and Drugs granted an evidentiary hearing before an administrative law judge on the proposal to withdraw approval of NDA 11–768 for Marax Tablets and NDA 12–879 for Marax Syrup, each containing theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. The NDA's are held by J. B. Roerig, Division of Pfizer, Inc. (Pfizer), 235 East 42d St., New York, NY 10017.

Other party participants were:

1. Barre-National, Inc., 4128 Haywood Ave., Baltimore, MD 21215 (Barre); Hydroxyzine Compound Syrup (no NDA).

2. Cord Laboratories, Inc. (now Geneva Pharmaceuticals, Inc.), 2555 West Midway Blvd., Broomfield, CO 80038 (Cord); Brofed Tablets (no NDA).

3. Barrows Research Group, Inc., 99 West Hawthorne Ave., Valley Stream, NY 11580 (Barrows). Unnamed drug product. Barrows later withdrew its hearing request.

Subsequently, in accordance with agreements to resolve, by other means, the issue of their drug products' effectiveness, Pfizer, Barre, and Cord withdrew their hearing requests. Under those agreements, FDA has concluded that Marax Tablets and Marax Syrup have not been shown to be effective, and FDA is now withdrawing approval of the NDA's for these products.

This notice applies to any drug product that is identical, related, or similar to these products and is not the subject of an approved NDA (21 CFR 310.6). Such products include Hydroxyzine Compound Syrup and Brofed Tablets, each of which contains theophylline, ephedrine sulfate, and hydroxyzine hydrochloride. Any person who wishes to determine whether a specific product is covered by this notice should write to the Division of Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and under the authority delegated to her (21 CFR 5.82), finds that on the basis of new information before her with respect to Marax Tablets and Marax Syrup, evaluated together with the evidence available to her when the applications were approved, there is a lack of substantial evidence that the products will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

Therefore, based on the foregoing finding, approvals and all the amendments and supplements thereto of NDA 11–768 and NDA 12–879 are withdrawn effective August 7, 1998. Shipment in interstate commerce of the products listed above or of any identical, related, or similar product that is not the subject of an approved NDA will then be unlawful.

Dated: June 15, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–18140 Filed 7–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appears in the **Federal Register** of June 25, 1998 (63 FR 34655). The notice announced a meeting of the Anti-Infective Drugs Advisory Committee, which was scheduled for July 29, 30, and 31, 1998. The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Carolyn C. Harris, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

In FR Doc. 98–16934 appearing on page 34655 in the **Federal Register** of Thursday, June 25, 1998, the following correction is made:

On page 34655, under the *Agenda* caption, in the 2d column, beginning in the 1st line, ''http://www.fda.gov/cder/guidance.htm'' is corrected to read ''http://www.fda.gov/cder/guidance/index.htm''.

Dated: July 1, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–18144 Filed 7–7–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Notice of Hearing: Reconsideration of Disapproval of New York Title XXI State Plan Amendment (SPA)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on July 29, 1998; 10:00 a.m., Thirty-Eighth floor, 26 Federal Plaza, New York, New York 10278 to reconsider our decision to disapprove New York Title XXI SPA.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by July 23, 1998.

FOR FURTHER INFORMATION CONTACT: Stan Katz, Presiding Officer, HCFA, C1–09–13, 7500 Security Boulevard, Baltimore, Maryland 21244, Telephone: (410)–786–2661.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove the New York Title XXI State Plan Amendment (SPA) submitted March 26, 1998.

Section 1116 of the Social Security Act (the Act) and 42 CFR Part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. These requirements are made applicable under

Title XXI by section 2107(e)(2)(B). The Health Care Financing Administration (HCFA) is required to publish a copy of the notice to the State that informs the State of the time and place of the hearing and the issues to be considered. If we subsequently notify the State of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as amicus curiae must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

New York submitted this SPA on March 26, 1998 to revise its approved Title XXI plan to change the effective date to October 1, 1997, from the previously approved date of April 15, 1998. This change in effective date would permit the State to claim enhanced matching payments for the operation of its Child Health Plus (CHP) program for the period from October 1, 1997 to April 14, 1998. The SPA was disapproved on April 1, 1998.

At issue in this reconsideration is whether the State is entitled to an effective date for its Title XXI plan which included a period during which the State was not operating a program which met the requirements of Title XXI (or the approved State plan). HCFA disapproved this SPA because of two elements of the State's CHP program, as in effect between October 1, 1997 and April 14, 1998, which were inconsistent with the requirements of Title XXI. First, premiums and cost sharing in effect during this period were inconsistent with the requirements of section 2103(e)(3)(A) of the Social Security Act. For example, the State CHP program provided for a $35 copayment for emergency services even if a child's family income was less than 150 percent of the poverty level. Also the CHP program permitted premiums for children with family incomes between 120 percent and 150 percent of the federal poverty level. Both of these charges were in amounts higher than those authorized under section 2103(e)(3)(A), which makes applicable the Medicaid premium and cost sharing limitations. Moreover, the State was not applying procedures to ensure ''that children found through * * * screening to be eligible for medical assistance under the State Medicaid plan under title XIX are enrolled for such assistance under such plan'' as required under section 2102(b)(3)(B) of the Social Security Act and guidance outlined in a letter to States on January 23, 1998.

Section 2106(c)(1) of the Act directs the Secretary to approve plans which ''substantially comply with the requirements'' of Title XXI. Under section 2106(a)(2)(B), a Title XXI plan ''shall be effective beginning with a calendar quarter that is specified in the plan, but in no case earlier than October 1, 1997.'' However, this flexibility is limited by the requirement in section 2106(d)(1) that ''[T]he State shall conduct the program in accordance with the plan (and any amendments) approved under subsection (c) and with the requirements of this title.'' Approval of the October 1, 1997 effective date was not warranted because the State was not operating its program in substantial compliance with the requirements of Title XXI or with the approved State plan during the period October 1, 1997 through April 14, 1998.

Under Section 2106(c) of the Social Security Act, the Secretary may approve, disapprove, or request additional information on a proposed Title XXI State Plan amendment within ninety days.

The Secretary has concluded that the State's amendment to its Title XXI Plan, submitted on March 26, 1998, to change the effective date of the plan, could not be approved because the State program during the period in question did not substantially comply with the requirements of Title XXI. Therefore, HCFA, in consultation with the Secretary, disapproved the amendment.

The notice to New York announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Barbara A. DeBuono, M.D.; M.P.H., Commissioner, State of New York, Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237.

Dear Ms. DeBuono: I am responding to your request for reconsideration of the decision to disapprove New York Title XXI State Plan Amendment (SPA) submitted March 26, 1998.

At issue in this reconsideration is whether the State is entitled to an effective date for its Title XXI plan which included a period during which the State was not operating a program which met the requirements of Title XXI (or the approved State plan).

Specifically, the premiums and cost sharing provisions for the State's Child Health Plus program, in effect during the period in which the State seeks retroactive approval through this amendment, were inconsistent with the requirements of section 2103 (a)(3)(A) of the Social Security Act. In addition, the State was not applying procedures to ensure ''that children found through * * * screening to be eligible for medical assistance under the State Medicaid plan under title XIX are enrolled for such assistance under such plan'' as required under section 2102(b)(3)(B) of the Social Security Act and guidance outlined in a letter to States on January 23, 1998.

I am scheduling a hearing on your request for reconsideration to be held on July 29, 1998 on the Thirty-Eighth Floor, 26 Federal Plaza, New York, New York 10278.

If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, Part 430.

I am designating Mr. Stanley Katz as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2661.

Sincerely,

Nancy-Ann Min DeParle,

Administrator.

Section 1116 of the Social Security Act (42 U.S.C. section 1316); 42 CFR section 430.18)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: June 29, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98–18019 Filed 7–2–98; 10:31 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; An Evaluation of the National Cancer Institute Science Enrichment Program

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institute of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* An Evaluation of the NCI Science