subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On May 12, 1995, Reed & Carnrick Pharmaceuticals submitted a citizen petition (Docket No. 95P–0128/CP1) under 21 CFR 10.25(a) and 10.30 requesting that the agency determine whether hydrocortisone acetate topical ointment 2.5% was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to keep the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Hydrocortisone acetate topical ointment 2.5%, along with the 1% strength, is the subject of approved NDA 8–917 held by the Upjohn Co. (Upjohn). On July 28, 1953, Upjohn obtained approval to market the 2.5% strength of hydrocortisone acetate topical ointment. Upjohn withdrew the drug from sale in 1991.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that hydrocortisone acetate topical ointment 2.5% was not withdrawn from sale for reasons of safety or effectiveness and will continue to list hydrocortisone acetate topical ointment 2.5% in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to hydrocortisone acetate topical ointment 2.5% may be submitted to the agency.

Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12690 Filed 5–20–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93P–0322]

Determination that Medroxyprogesterone Acetate 100 Milligrams per Milliliter Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that medroxyprogesterone acetate (Depo-Provera®) 100 milligrams per milliliter (mg/mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow sponsors to submit abbreviated new drug applications (ANDA's) for medroxyprogesterone acetate 100 mg/mL.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On August 30, 1993, King & Spalding submitted a citizen petition (Docket No. 93P–0322/CP1) under 21 CFR 10.25(a) and 10.30 requesting that the agency determine whether medroxyprogesterone acetate 100 mg/mL was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to keep the drug in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' Medroxyprogesterone acetate 100 mg/mL, along with the 400 mg/mL strength, is the subject of approved NDA 12–541 held by the Upjohn Co. (Upjohn). On December 1, 1992, Upjohn withdrew medroxyprogesterone acetate 100 mg/mL from sale.

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that medroxyprogesterone acetate 100 mg/mL was not withdrawn from sale for reasons of safety or effectiveness and will continue to list medroxyprogesterone acetate 100 mg/mL in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to medroxyprogesterone acetate 100 mg/mL may be submitted to the agency.

FDA has also considered the comment submitted by Upjohn, dated November 19, 1993, opposing an FDA determination that medroxyprogesterone acetate 100 mg/mL was withdrawn from the market for reasons other than safety or effectiveness. The comment does not contain any information indicating that the drug was withdrawn for reasons of safety or effectiveness, but rather indicates that Upjohn did not perceive a need to keep medroxyprogesterone

acetate in a 100 mg/mL strength on the market because the 400 mg/mL strength, which Upjohn also marketed, was viewed as a more convenient strength for the approved indication of adjunctive therapy and palliative treatment of inoperable recurrent and metastatic endometrial or renal carcinoma.

Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12760 Filed 5–21–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the following National Institute of Mental Health Special Emphasis Panel.

The meeting will be open to the public to provide concept review of proposed contract or grant solicitations.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the contact person named below in advance of the meeting.

Name of Committee: National Institute of Mental Health Special Emphasis Panel (Telephone Conference Call)

Date: May 22, 1996.

Time: 1:30 p.m.

Place: Parklawn Building, Room 9–105, 5600 Fishers Lane, Rockville, MD 20857.

Agenda: To provide concept review for a contract project entitled ''Pilot Study of Verapamil in Females with Bipolar Disorder.''

Contact Person: Michael J. Moody, Contracts Review Coordinator, Parklawn Building, Room 9–105, 5600 Fishers Lane, Rockville, MD 20857, Telephone 301, 443–3367.

This notice is being published less than 15 days prior to the above meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, 93.281, 93.282)

Dated: May 16, 1996.

Anna Snouffer,

Committee Management Specialist, NIH.

[FR Doc. 96–12857 Filed 5–17–96; 1:41 pm]

BILLING CODE 4140–01–M

Substance Abuse and Mental Health Services Administration

Programmatic Supplement to the Cooperative Agreement With the National Association of State Mental Health Program Directors

AGENCY: Center for Mental Health Services (CMHS), Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Planned single-source supplemental award to assist State mental health, substance abuse, and Medicaid officials to develop pragmatic performance measures and outcome indicators for use in Medicaid managed behavioral health care contracting.

SUMMARY: This notice is to provide information to the public concerning a planned programmatic supplement to an ongoing cooperative agreement between the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) and the National Association of State Mental Health Program Directors (NASMHPD). The ongoing cooperative agreement funds the Technical Assistance Center for State Mental Health Planning. The programmatic supplement is being provided to address a need that arose from the recommendations of the SAMHSA Conference—Partnerships for Change. The conference highlighted national and State trends in organizing and financing public mental health and substance abuse care. Federal and State officials received strong encouragement to expand their collaboration across levels of government and between mental health, substance abuse, and Medicaid agencies to prepare for rapid changes in their roles, responsibilities, and funding. A particularly acute need identified was a core set of quality assurance and performance measures that public purchasers of managed behavioral health care services could use to monitor the new contracting mechanism. In the absence of a core set of measures, it is possible that persons with severe and persistent mental illnesses, chronic substance abuse disorders, and children and adolescents with serious emotional problems may be placed into managed care systems with inadequate safeguards and controls. In fact, the network of community-based services that has been developed with great difficulty over the last three decades may be jeopardized if public sector managed care contracts lack essential performance standards and quality assurance guidelines.

The NASMHPD Board of Directors, in close collaboration with the NASMHPD Research Institute, and the Boards of Directors of the National Association of State Alcohol and Drug Abuse Directors (NASADAD) and the American Public Welfare Association (APWA), have all identified as their top mutual priority the development of performance measurement indicators that could be used by States that are letting contracts for Medicaid managed behavioral health care. NASMHPD, which represents the State mental health agencies in every State, has a long history of facilitating the voluntary collection of uniform mental health data across States. NASMHPD has worked with State mental health agencies and CMHS on the Mental Health Statistics Improvement Program (MHSIP) to foster the collection, analysis, and reporting of data which are useful for systems management, policy decisions, evaluation, performance assessment, and research in the States, as well as nationally. State health care reform efforts and the introduction of managed care financial arrangements have placed new demands on States for quality assurance and accountability information. NASMHPD's Technical Assistance Center cooperative agreement with CMHS represents a unique capacity that does not exist anywhere else. The NASMHPD Technical Assistance Center works closely with every State mental health agency. A supplement to the existing cooperative agreement will allow the NASMHPD Technical Assistance Center to develop a consensus among State mental health, substance abuse, and Medicaid agencies around the collection of information about managed care that can be used internally by States for quality assurance and contract monitoring purposes, while, at the same time, assuring cooperation across States so that data items and data collection procedures are uniform so that valid national and cross-state comparisons can be made. Therefore, SAMHSA's CMHS has determined that a supplement to the existing cooperative agreement with NASMHPD should be made to carry out this important work.

This notice is not a request for applications; only NASMHPD is eligible to apply for the supplement to the existing cooperative agreement. If the NASMHPD supplemental application is recommended for approval by the Special Review Committee, funds will be made available.

Authority: The programmatic supplement to the ongoing cooperative agreement will be made under the authority of Section 1948(a)