Park Labs, Inc. (formerly Clay Park Laboratories), 1700 Bathgate Ave., Bathgate Industrial Park, Bronx, NY 10457.

NMC Laboratories, 70–36 83d St., Glendale, NY 11385, filed a hearing request without reference to a particular product.

In a document published in the Federal Register of April 17, 1985 (50 FR 15227), FDA announced conditions for approval and marketing of reformulations of both the cream and ointment products that omit neomycin sulfate and gramicidin. FDA subsequently approved supplemental NDA's providing for reformulation of all the products listed above.

The drug manufacturers listed above have since withdrawn their hearing requests. Accordingly, FDA is now withdrawing approval of those parts of the NDA's listed above pertaining to the products containing neomycin sulfate and gramicidin.

Antibiotic drug monographs for nystatin-neomycin sulfate-gramicidin-triamcinolone acetonide ointment and cream products are cited in 21 CFR 449.550c and 449.550e, respectively. These monographs will be modified in a future Federal Register notice, if necessary. In accord with the plans announced by President Clinton on March 4, 1995, regarding reform of the Federal regulatory system as part of the Administration's ''Reinventing Government'' initiative, the agency has initiated the consideration of legislation that would eliminate the need for publication of antibiotic monographs.

Any drug product that is identical, related, or similar to the products listed above and is not the subject of an approved NDA is covered by the NDA's 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 Prescription Drug Compliance and Surveillance (address above).

The Director of the Center for Drug Evaluation and Research, under section 505(e) of the act and under authority delegated to her (21 CFR 5.82), finds, on the basis of new information before her with respect to the cream and ointment products containing neomycin sulfate and gramicidin, evaluated together with the evidence available to her when the applications were approved, that 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, pursuant to the foregoing finding, approval of those parts of NDA 60–576 and NDA 60–572 that provide for Mycolog Cream and Ointment, respectively; those parts of NDA 61–954 and NDA 62–045 that provide for Myco Triacet Cream and Ointment, respectively; those parts of NDA 62–135 and NDA 62–136 that provide for the cream and ointment, respectively; and those parts of NDA 62–l86 and NDA 62–280 that provide for the cream and ointment, respectively, containing neomycin sulfate and gramicidin, and all the amendments and supplements for these products, is withdrawn effective September 16, 1996. Shipment in interstate commerce of the products above or any identical, related, or similar product that is not the subject of an approved new drug application will be unlawful as of that effective date.

Dated: June 28, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–20899 Filed 8–15–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 91N–0295]

RIN 0910–AA09

Medical Devices; Methods to Estimate Medical Device Denominator Data; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to gather and exchange information regarding the methods used by the medical device industry to derive estimates of numbers of devices manufactured, distributed, and in current use (collectively referred to as denominator data) for purposes of submitting baseline reports as required in the December 1995 medical device report (MDR) final rule. This workshop is intended to help FDA better understand these methods and therefore to better evaluate and utilize the denominator data.

DATES: The public workshop will be held on September 17, 1996, from 8:30 a.m. to 6 p.m. Submit registration forms by September 10, 1996. Persons wishing to make formal comments at the workshop must submit a request with outline of their presentation on or before September 3, 1996.

ADDRESSES: The public workshop will be held at the Parklawn Building, 5600 Fishers Lane, Conference Rooms D and E, Rockville, MD 20857. A proposed agenda and registration forms can be obtained after August 15, 1996, through the Center for Devices and Radiological Health (CDRH) Facts-on-Demand system. To receive these documents via FAX call the CDRH Facts-on-Demand system at 1–800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number, 1053, followed by the pound sign (#), then follow the remaining voice prompts to complete your request. Submit registration forms and requests to make formal comments to the contact person below. A transcript of the meeting may be available from the DSMA Facts line as of October 4, 1996.

FOR FURTHER INFORMATION CONTACT: Roselie A. Bright, Center for Devices and Radiological Health (HFZ–541), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–0600.

FDA is soliciting speakers from the industry to speak on methods they use to estimate denominator data. Speakers representing these categories of devices are being sought: Single use/disposable, multiple use, and implantables. If you are interested in speaking, please call the contact person as soon as possible. Speakers are asked to limit their presentations to 10–15 minutes. There is no registration fee, but advance registration is required due to space limitations. If you have a disability that affects your attendance at, or participation in, this meeting, please send a letter to the contact person and identify your needs. The availability of appropriate accommodations cannot be assured unless prior written notification is provided.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 11, 1995 (60 FR 63578), the agency published the MDR final rule. On April 11, 1996, (61 FR 16043), FDA announced the effective date of the MDR final rule was extended to July 31, 1996. On July 31, 1996 (61 FR 39868), the agency issued a stay of the effective date for certain provisions of the MDR final rule regarding baseline reporting requirements.

Under the December 11, 1995, final rule, manufacturers are required to submit individual reports of adverse events on a monthly basis, as well as annual baseline reports. Baseline reports are required, under § 803.55 (21 CFR 803.55), to include information specifically identifying a device for which an adverse event has been submitted. Under § 803.55, manufacturers are also required to

submit denominator data for the device identified, which includes the number of devices manufactured and distributed in the last 12 months, an estimate of the number of devices in current use, and a brief description of any methods used to estimate the number of devices distributed and in current use. Based on comments received subsequent to the issuance of the December 11, 1995, final rule, FDA stayed the requirement to submit this denominator data pending further evaluation (61 FR 39868).

During the stay, FDA has two projects planned: (1) A public workshop and (2) a demonstration project. The agency is requesting industry's assistance to accomplish both these projects. In preparation for the demonstration project, CDRH is convening a public workshop to enable the agency to better understand methods used to derive denominator estimates and therefore better evaluate and utilize these data.

For this workshop, CDRH is soliciting speakers from the medical device industry to speak for approximately 10–15 minutes each on methods they use to estimate denominator data. Given that methods may vary by type of device, FDA is interested in hearing from members of the medical industry representing three basic categories of devices: Single use/disposable, multiple use, and implantables. After opening remarks and background presentations by FDA, it is anticipating that the workshop will include a series of presentations by industry members representing these basic device categories in three sessions (one per category) over 1 to 2 days. FDA intends to invite a group of discussants, representing various disciplines (e.g., survey methods, statistics, procurement, marketing, epidemiology), to listen and to respond to the presentations. Several question and answer sessions are also planned for the benefit of attendees.

At the completion of the public workshop and the demonstration project, the agency will either lift the stay of the December 1995 final rule baseline denominator reporting requirements, retain the stay, or issue a new proposed rule to modify these requirements.

Dated: August 12, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20965 Filed 8–15–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[ORD–090–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: June 1996

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

ACTION: Notice.

SUMMARY: During the month of June, one new proposal for a Medicaid demonstration project was submitted to the Department of Health and Human Services, one proposal was approved and one proposal was withdrawn. No proposals were disapproved during this time period. (This notice can be accessed on the Internet at HTTP://WWW.HCFA.GOV/ORD/ORDHP1.HTML.)

COMMENTS: We will accept written comments on these proposals. We will, if feasible, acknowledge receipt of all comments, but we will not provide written responses to comments. We will, however, neither approve nor disapprove any new proposal for at least 30 days after the date of this notice to allow time to receive and consider comments. Direct comments as indicated below.

ADDRESSES: Mail correspondence to: Susan Anderson, Office of Research and Demonstrations, Health Care Financing Administration, Mail Stop C3–11–07, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Susan Anderson, (410) 786–3996.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 1115 of the Social Security Act (the Act), the Department of Health and Human Services (HHS) may consider and approve research and demonstration proposals with a broad range of policy objectives. These demonstrations can lead to improvements in achieving the purposes of the Act.

In exercising her discretionary authority, the Secretary has developed a number of policies and procedures for reviewing proposals. On September 27, 1994, we published a notice in the Federal Register (59 FR 49249) that specified (1) the principles that we ordinarily will consider when approving or disapproving demonstration projects under the authority in section 1115(a) of the Act; (2) the procedures we expect States to use in involving the public in the development of proposed demonstration projects under section 1115; and (3) the procedures we ordinarily will follow in reviewing demonstration proposals. We are committed to a thorough and expeditious review of State requests to conduct such demonstrations.

As part of our procedures, we publish a notice in the Federal Register with a monthly listing of all new submissions, pending proposals, approvals, disapprovals, and withdrawn proposals. Proposals submitted in response to a grant solicitation or other competitive process are reported as received during the month that such grant or bid is awarded, so as to prevent interference with the awards process.

II. Listing of New, Pending, Approved, and Withdrawn Proposals for the Month of June 1996

A. Comprehensive Health Reform Programs

1. New Proposals

The following comprehensive health reform proposal was received during the month of June:

Demonstration Title/State: Community Care Systems—New Hampshire.

Description: The State submitted a revised proposal for ''Community Care Systems.'' This system will provide capitated, managed acute care services and coordination for specialty and support services not included in the health plan service package. The State proposes to implement this program in three phases: Phase 1 will enroll AFDC and AFDC-related children and families; Phase 2 will enroll the elderly population; and Phase 3 will enroll disabled adults and disabled children. The current waiver request is for Phase 1 only.

Date Received: June 5, 1996.

State Contact: Lorrie Lutz, Planning and Policy Development, State of New Hampshire, Department of Health and Human Services, 6 Hazen Drive, Concord, NY 03301–6505, (603) 271–4478.

Federal Project Officer: Cindy Shirk, Health Care Financing Administration, Office of Research and Demonstrations, Office of State Health Reform Demonstrations, Mail Stop C3–18–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

2. Pending, Approved and Disapproved Proposals

We did not approve or disapprove any proposals during the month of June. The one new proposal submitted in May and now pending is as follows:

Demonstration Title/State: Maryland Medicaid Reform Proposal—Maryland.