bodied applicants and recipients to do job search for up to 16 weeks unless otherwise exempted; terminate the case when there is loss of contact with the client for 1 month after nonpayment for failure to meet the performance requirements; exclude the earned income and resources of a dependent child who is a full-time high school student; allow payment of the supplied shelter grant for households with a SSI recipient, unmarried minor parents, or recipients disqualified for other reasons (fraud, education time limits, illegal aliens); exclude one licensed vehicle with a fair market value of less than $12,000; increase the resource limit to $2,500 for those in compliance with, or exempted from, the performance requirements; and exclude veteran's service connected disability compensation if the annual income is less than the poverty level.

Date Received: 5/13/96.

Type: Combined AFDC/Medicaid.

Current Status: Pending.

Contact Person: Marianne Lee, (307) 777–6849.

III. Listing of Approved Proposals Since July 1, 1995

Project Title: Tennessee—Families First.

Contact Person: Glenda Shearon, (615) 313–5652.

Project Title: Utah—Single-Parent Employment Demonstration (Amendments).

Contact Person: Bill Biggs, (801) 538–4337.

IV. Requests for Copies of a Proposal

Requests for copies of an AFDC or combined AFDC/Medicaid proposal should be directed to the Administration for Children and Families (ACF) at the address listed above. Questions concerning the content of a proposal should be directed to the State contact listed for the proposal.

(Catalog of Federal Domestic Assistance Program, No. 93562; Assistance Payments—Research)

Dated: August 12, 1996.

Howard Rolston,

Director, Office of Planning, Research and Evaluation.

[FR Doc. 96–20938 Filed 8–15–96; 8:45am]

BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 93F–0269]

Lonza, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 3B4387), proposing that the food additive regulations be amended to provide for the safe use of didecyldimethylammonium chloride as a preservative on wooden articles intended to contact food.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of August 12, 1993 (58 FR 42977), FDA announced that a food additive petition (FAP 3B4387) had been filed on behalf of Lonza, Inc., c/o Delta Analytical Corp., 7910 Woodmont Ave., suite 1000, Bethesda, MD 20814 (currently c/o Lewis & Harrison, 122 C St. NW., suite 740, Washington, DC 20001).

The petition proposed to amend the food additive regulations in § 178.3800 *Preservatives for wood* (21 CFR 178.3800) to provide for the safe use of didecyldimethylammonium chloride as a preservative on wooden articles intended to contact food. Lonza, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 19, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–20964 Filed 8–15–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 80N–0012 and 84N–0067; DESI 10826]

Drug Efficacy Study Implementation; Certain Topical Anti-Infective Drug Products; Withdrawal of Approval of New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of pertinent parts of the new drug applications (NDA's) for cream and ointment products containing neomycin sulfate and gramicidin in addition to nystatin and triamcinolone acetonide. There is a lack of substantial evidence that the products as originally formulated are effective in the treatment of various dermatoses and as anti-infective agents for which they are labeled. Both products have been reformulated to eliminate neomycin sulfate and gramicidin, and FDA has approved the reformulated products as safe and effective.

EFECTIVE DATE: September 16, 1996.

ADDRESSES: Requests for guidance on the applicability of this notice to a specific product should be identified with the Drug Efficacy Study Implementation (DESI) number 10826 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: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In a notice of opportunity for a hearing published in the Federal Register of September 25, 1981 (46 FR 47408), the Director of the Bureau of Drugs (now the Center for Drug Evaluation and Research) proposed to withdraw approval of NDA's for certain topical anti-infective drug products. The proposal was based on the lack of substantial evidence of effectiveness as required by section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and 21 CFR 314.126 (previously 21 CFR 314.111(a)(5)). In response to that notice, requests for a hearing were filed for the following NDA's:

1. NDA's 60–572 and 60–576; Mycolog Ointment and Cream, respectively, both containing nystatin (100,000 units per gram (g)), triamcinolone acetonide (1.0 milligram (mg)/g), neomycin sulfate (2.5 mg/g), and gramicidin (0.25 mg/g); now held by Apothecon, a division of Bristol-Myers Squibb, P.O. Box 4500, Princeton, NJ 08543–4500.

2. NDA's 61–954 and 62–045; Myco Triacet Cream and Ointment, respectively, containing nystatin, neomycin sulfate, gramicidin, and triamcinolone acetonide; held by Lemmon Co., 650 Cathill Rd., Sellersville, PA 18960.

3. NDA's 62–135 and 62–136; Nystatin-Neomycin Sulfate-Gramicidin-Triamcinolone Acetonide Ointment and Cream, respectively; held by E. Fougera and Co. (formerly Byk Pharmaceutical Group), a division of Altana, Inc., 60 Baylis Rd., Melville, NY 11747.

4. NDA's 62–186 and 62–280; Nystatin-Neomycin Sulfate-Gramicidin-Triamcinolone Acetonide Cream and Ointment, respectively; held by Clay-

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