FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in Tables 1 and 2 of this document. Based on the trend in the past 3 years, an estimated 5,000 submissions are expected each year. FDA's administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that an average of 80 hours are required to prepare a submission (exclusive of preparing clinical data, research, etc.). FDA, therefore, estimates that a total of 400,000 hours of effort is required for the 5,000 submissions. It is also estimated that the respondents will receive requests for an average of 20,000 documents. At an estimated one-half hour to process these documents, an additional 10,000 recordkeeping hours are expected for this program.

Dated: May 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14917 Filed 6–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0182]

KV Pharmaceutical Co.; Withdrawal of Approval of Two Abbreviated New Drug Applications and One Abbreviated Antibiotic Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two abbreviated new drug applications (ANDA's) and one abbreviated antibiotic drug application (AADA) held by KV Pharmaceutical Co. (KV), 2503 South Hanley Rd., St. Louis, MO 63144. This action is being taken because the applications contain untrue statements of material fact, and the drugs covered by these applications lack substantial evidence of effectiveness.

EFFECTIVE DATE: June 5, 1998.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 1995 (60 FR 32982), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of the following abbreviated applications:

AADA 62–047, Erythromycin Ethylsuccinate Oral Suspension, 200 and 400 milligrams (mg);

ANDA 71–929, Disopyramide Phosphate Extended Release Capsules, 100 mg; and

ANDA 86–538, Nitroglycerin Extended Release Capsules, 2.5 mg.

The grounds for the proposed withdrawals were: (1) That the applications contained untrue statements of material fact, and (2) that based upon new information evaluated together with the evidence available when the applications were approved, there is a lack of substantial evidence that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

On July 26, 1995, KV requested a hearing. Subsequently, in a letter dated August 25, 1995, KV withdrew its request for a hearing and requested withdrawal of these applications because the products are no longer being marketed. (AADA 62–047 was inadvertently included in a previous **Federal Register** notice (61 FR 13506, March 27, 1996) that withdrew a large number of applications based on the request of the applicants.)

Based on the information presented in the June 26, 1995, notice, the Director of the Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and under authority delegated to her (21 CFR 5.82), finds that the applications listed above contain untrue statements of material fact (21 U.S.C. 355(e)(5)); and that on the basis of new information before her with respect to the drugs, evaluated together with the evidence available to her when the applications were approved, there is a lack of substantial evidence that the drugs will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling (21 U.S.C. 355(e)(3)).

Therefore, approval of the applications listed above, and all their amendments and supplements, is hereby withdrawn, effective June 5, 1998. Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action.

Section 505(j)(7)(C) of the act requires that FDA immediately remove from its approved product list (''Approved Drug Products with Therapeutic Equivalence Evaluation'') (''the list'') any drug whose approval was withdrawn for grounds described in the first sentence of section 505(e) of the act. Such grounds apply to this withdrawal. Notice is hereby given that the drugs covered by these applications are removed from the list.

Dated: May 28, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–14914 Filed 6–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Food Advisory Committee. This meeting was announced in the **Federal Register** of May 12, 1998 (63 FR 26194). The amendment is being made to reflect a change in the *Procedure* portion of the meeting notice. The organization and time of the oral presentations have been changed. All oral presentations will be made on June 16, 1998. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), 202–205–4727, or Catherine M. DeRoever (HFS–22), 202–205–4251, FAX 202–205–4970, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 12, 1998 (63 FR 26194), FDA announced that oral presentations from the public during the Food Advisory Committee meeting would be scheduled in three sessions over 2 days. However, all oral presentations have been combined into one session. On page 26195, in the first column, the *Procedure* portion of this meeting notice is amended to read as follows:

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 5, 1998. All oral presentations are scheduled in a

combined session on June 16, 1998, 8 a.m. to 10 a.m. * * *.

Dated: June 1, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–15149 Filed 6–3–98; 11:35 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)2(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Health Service Corps—A Uniform Data System (New)

This is a request for approval to authorize the National Health Service Corps (NHSC), Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA) to implement a modified version of the existing BPHC Universal Data System (OMB No. 0915–0093) to collect data from BPHC non-grant supported sites (NHSC Free Standing Sites) in response to Federal mandates for reports and in support of efficient and effective program management. A 60-day notice for this project was published in FR6241966 under the Title Reporting Requirements for the National Health Service Corps (NHSC) non-grant sites. The project has been revised to reflect an increased number of respondents and response burden.

The National Health Service Corps (authorized by the Public Health Service Act, Section 331) needs to collect data on its programs to ensure compliance with legislative mandates and to report to Congress and policymakers on program accomplishments. To meet these objectives, the NHSC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The NHSC will provide data on services, staffing, and financing.

Specifically each site will be asked to complete the following six tables:

1. Services offered and delivery method
2. Users by various characteristics
3. Staffing and utilization
4. Charges and collections
5. Receivables, income and expenses
6. Managed care

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Hours per response	Total burden hours
Universal Report	620	27	16,740

Send comments to HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD, 20857. Written comments should be received within 60 days of this notice.

Dated: May 28, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–14924 Filed 6–4–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 1998.

Name: National Advisory Council (NAC) on the National Health Service Corps (NHSC).

Date and Time: June 11, 1998; 6:00 p.m.–9:00 p.m.; June 12, 1998; 7:30 a.m.–5:00 p.m.; June 13, 1998; 8:00 a.m.–6:00 p.m.; June 14, 1998; 8:00 a.m.–11:00 a.m.

Place: Hotel Sofitel, 5601 W. 75th Street, Bloomington, Minnesota 55439, (612) 835–1900.

The meeting is open to the public. For further information, call Ms. Eve Morrow at (301) 594–4144.

Agenda: items include updates on the NHSC program; reports from the State organization representatives and drafting the blueprint for the NHSC of the 21st century.

Agenda items are subject to change as priorities dictate.

Dated: May 29, 1998.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–14923 Filed 6–4–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to Section 19(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel meeting:

Name of SEP: ZDKI GRB–B C2.

Date: June 3, 1998.

Time: 12:00 Noon.

Place: Room 6AS–25S, Natcher Building, NIH (Telephone Conference Call).

Contact: Ned Feder, M.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS–25S, National Institutes of Health, Bethesda, Maryland 20892–6600, Phone: (301) 594–8890.

Purpose/Agenda: To review and evaluate grant applications.