In future **Federal Register** notices, FDA will advise applicants for the products not yet using the new Form FDA 356h, when they may voluntarily begin, and when they will be required to use the new Form FDA 356h. FDA is in the process of preparing guidance documents on the content and format of the chemistry, manufacturing, and controls section, and establishment description section of the new Form FDA 356h for those biological products not yet using the new form. As these guidance documents are completed, FDA will begin accepting the new Form FDA 356h. Until further notice, if the biological product is not specified in § 601.2(c), applicants should continue to submit an ELA and a PLA application on the CBER forms listed below in this notice.

This collection of information involves the following forms: Form FDA 2599, ''Establishment License Application for the Manufacture of Blood and Blood Components;'' Form FDA 2599a, ''Supplement to Establishment License Application for the Manufacture of Blood and Blood Components;'' Form FDA 2600, ''Product License Application for the Manufacture of Source Plasma;'' Form FDA 2600b, ''Product License Application for Therapeutic Exchange Plasma;'' Form FDA 3066, ''Product License Application for Manufacture of Blood Grouping Reagents;'' Form FDA 3086, ''Product License Application for the Manufacture of Reagent Red Blood Cells;'' Form FDA 3096, ''Product License Application for the Manufacture of Anti-Human Globulin;'' Form FDA 3098, ''Product License Application for the Manufacture of Whole Blood and Blood Components;'' Form FDA 3098a, ''Product License Application for Red Blood Cells;'' Form FDA 3098b, ''Product License Application for Plasma;'' Form FDA 3098c, ''Product License Application for Platelets;'' Form FDA 3098d, ''Product License Application for Cryoprecipitated Antihemophilic Factor;'' Form FDA 3098e, ''The Manufacture of Products Prepared by Cytapheresis;'' Form FDA 3210, ''Application for Establishment License for Manufacture of Biological Products;'' Form FDA 3213, ''Application for License for the Manufacture of Allergenic Products;'' Form FDA 3214, ''Application for the Manufacture of a Human Plasma Derivative;'' and Form FDA 3314, ''Product License Application for the Manufacture of Human Immunodeficiency Virus for In-Vitro Diagnostic Use.''

Respondents to this collection of information are manufacturers of biological products. The reporting burden for the current collection of information using CBER's license application forms under OMB control number 0910–0124 was reported to OMB as part of the total burden for the agency's collection of information using Form FDA 356h. This collection of information using Form FDA 356h was assigned OMB control number 0910–0338 and approved by OMB on April 23, 1997. The approval for OMB control number 0910–0338 expires on April 30, 2000. The announcement of OMB's approval was published in the **Federal Register** of May 19, 1997 (62 FR 27262).

Under OMB control number 0910–0338, FDA estimated that CBER's portion of the reporting burden for collection of information using Form FDA 356h was 76,200 hours. The 76,200 hours reflected the future use of Form FDA 356h by all manufacturers of biological products. The number of manufacturers of biological products that are already using Form FDA 356h would account for approximately 3,000 hours of the total burden hours. The other 73,200 hours would account for manufacturers who may not have completed the transition to using Form FDA 356h and still need to use other license application forms. FDA expects that all manufacturers of biological products will begin to use Form FDA 356h during 1998. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Forms	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
601.2 and 601.12	FDA 2599, 2599a, 2600, 2600b, 3066, 3086, 3096, 3098, 3098a, 3098b, 3098c, 3098d, 3098e, 3210, 3213, 3214, and 3314	376	4.9	1,830	40	73,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14916 Filed 6–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0336]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and each proposed reinstatement of an existing collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on premarket notification submission 510(k), subpart E, to require a person/manufacturer who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for

introduction into interstate commerce, for commercial distribution of a device intended for human use.

DATES: Submit written comments on the collection of information by August 4, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Notification Submission 510(k), Subpart E—(OMB Control Number 0910–0120—Reinstatement)

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) and the implementing regulation, 21 CFR 807.81, require a person/manufacturer who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use.

Section 510(k) of the act allows for exemptions to the 510(k) submissions, i.e., a premarket notification submission would not be required if FDA determines that premarket notification is not necessary for the protection of the public health, and they are specifically exempted through the regulatory process. Under 21 CFR 807.85, ''Exemption from premarket notification,'' a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution. In addition, the device must meet one of the following conditions: (1) It is intended for use by a patient named in order of the physician or dentist (or other specially qualified persons), or (2) it is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if the device was legally in commercial distribution before May 28, 1976, or a premarket notification was submitted by another person.

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not devices can be allowed to enter the U.S. market. The premarket notification review process allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject and will not violate the subject's rights. The respondents to this information collection will primarily be medical device manufacturers and businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.81 and 807.87	5,000	1	5,000	80	400,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Response	Total Hours
807.93	2,000	10	20,000	0.5	10,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

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