public. 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 February 17, 2001. Oral presentations from the public will be scheduled between approximately 11:10 a.m. and 11:40 a.m., and between approximately 2:40 p.m. and 3:10 p.m. on March 5, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 21, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On March 5, 2001, from approximately 3:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion will be closed to permit discussion of these materials.

FDA regrets that it was unable to publish this notice 15 days prior to the March 5, 2001, Allergenic Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Allergenic Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 14, 2001.

Bonnie H. Malkin,

Special Assistant to the Senior Associate Commissioner.

[FR Doc. 01–4230 Filed 2–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0057]

Determination That Bethanechol Chloride Injection and Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 bethanechol chloride 5 milligrams (mg) per milliliter (mL) injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets, all formerly marketed by Merck & Co., Inc. (Merck), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDA's) for bethanechol chloride drug products, and it will also allow FDA to continue to approve ANDA's for bethanechol chloride drug products.

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

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products 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. Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 to which the ANDA refers.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), 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,'' 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 (21 CFR 314.162). Under § 314.161(a)(2) (21 CFR 314.161(a)(2)) the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDA's that refer to the drug that was withdrawn are approved. Section 314.161(d) provides that if FDA determines that the listed drug was removed from sale for safety or effectiveness reasons, the agency will begin proceedings to withdraw approval of the ANDA's that refer to the drug that was withdrawn from sale.

FDA has received a letter, dated April 7, 2000, from Merck, holder of NDA 6–536 for bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets, stating that Merck has withdrawn those products from sale. Danbury Pharmacal, Inc., Roberts Laboratories, Inc., Glenwood, Inc., and Sidmak Laboratories, Inc. (Sidmak), all hold approved ANDA's that refer to one or more of Merck's bethanechol chloride drug products. Merck sold its bethanechol chloride drug products under the trade name of Urecholine. In their April 7, 2000, letter, Merck also informed FDA that Merck has assigned the trademark Urecholine to Sidmak for use in the sale of Sidmak's bethanechol chloride drug products.

FDA has reviewed its records and, under § 314.161, has determined that bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will list Merck's bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. The approval status of the ANDA's that refer to bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets is unaffected. ANDA's for bethanechol chloride 5-mg/mL injection and bethanechol chloride 5-, 10-, 25-, and 50-mg tablets may be approved by the agency.

Dated: February 14, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–4229 Filed 2–20–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–9044]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration

(HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Provider Reimbursement Manual, Part 1—Chapter 27, Section 2721, 2722 and 2725, Request for Exception to ESRD Composite Rates and Supporting Regulations in 42 CFR 413.170 and 413.184; *Form No.:* HCFA–9044 (OMB# 0938–0296); *Use:* Sections 2721, 2722 and 2525 of the Provider Reimbursement Manual describe the information ESRD facilities must submit in justifying an exception request to their composite rate for outpatient dialysis services.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions and Federal Government; *Number of Respondents:* 291; *Total Annual Responses:* 291; *Total Annual Hours:* 14,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's Web Site Address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch,Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 25, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–4256 Filed 2–20–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds in the HRSA Preview; Withdrawal

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: In the **Federal Register** notice of Friday, July 7, 2000, in Part III ''Availability of Funds Announced in the HRSA Preview'' of FR Doc. 00–16874, on page 42217, the grant category beginning in the first column under the heading ''Partnership for Information and Communication (PIC) MCH Cooperative Agreements, CFDA# 93.110G,'' is withdrawn from competition because no competition is needed to fund all potential eligibles for this fiscal year. Prospective applicants have been notified directly of this withdrawal.

FOR FURTHER INFORMATION CONTACT: Sue Martone, Division of Child, Adolescent and Family Health, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–30, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone 1–301–443–2250.

Dated: February 14, 2001.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 01–4232 Filed 2–20–01; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds in the HRSA Preview; Correction

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice; correction.

SUMMARY: In the **Federal Register** notice of Friday, July 7, 2000, in Part III ''Availability of Funds Announced in the HRSA Preview'' of FR Doc. 00–16874, on page 42225, the grant category beginning in the first column under the heading ''Healthy Start Initiative (HSI)—Eliminating Disparities in Perinatal Health—Border Health, CFDA# 93.926N,'' is amended to further extend eligibility to applicants in Hawaii and Alaska who meet all requirements for this competition other than proximity to the Mexican border. These requirements include changes enumerated in item (4) of our **Federal Register** notice of Monday, December 4, 2000, in FR Doc. 00–30824, page 75721, beginning in the second column.

FOR FURTHER INFORMATION CONTACT: David de la Cruz, Division of Perinatal Systems and Women's Health, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–30, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone 1–301–443–8427.

Dated: February 14, 2001.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 01–4231 Filed 2–20–01; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4655–N–02]

Notice of Proposed Information Collection: Comment Request; Mortgage Record Change

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 23, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Silas C. Vaughn, Single Family Insurance Operations Division,