program, covering program savings, reductions in cost sharing, impacts on access to and quality of affected goods and services, and beneficiary satisfaction. This project's purpose is to provide information for this Report to Congress. *Form Number:* CMS–10197 (OMB#: 0938-–New); *Frequency:* Reporting—Other: Baseline and Follow-up; *Affected Public:* Individuals or Households, Business or other for-profit, Federal Government and Not-for-profit institutions; *Number of Respondents:* 12,671; *Total Annual Responses:* 12,671; *Total Annual Hours:* 6,557.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR 423.505; *Use:* Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Data will be validated, analyzed, and utilized for trend reporting by CMS. If outliers or other data anomalies are detected, CMS will work in collaboration with other CMS divisions for follow-up and resolution. *Form Number:* CMS–10185 (OMB#: 0938–0992); *Frequency:* Reporting: Quarterly and Semi-annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 3,203; *Total Annual Responses:* 12,812; *Total Annual Hours:* 102,496.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease (ESRD) Network Semi-Annual Cost Report Forms and Supporting Regulations in 42 CFR 405.2110 and 42 CFR 405.2112; *Use:* Section 1881(c) of the Social Security Act establishes End Stage Renal Disease (ESRD) Network contracts. The regulations designated at 42 CFR 405.2110 and 405.2112 designated 18 ESRD Networks which are funded by renewable contracts. These contracts are on 3-year cycles. To better administer the program, CMS is requiring contractors to submit semi-annual cost reports. The purpose of the cost reports is to enable the ESRD Networks to report costs in a standardized manner. This will allow CMS to review, compare and project ESRD Network costs during the life of the contract. *Form Number:* CMS–685 (OMB#: 0938–0657); *Frequency:* Reporting—Semi-annually; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 18; *Total Annual Responses:* 36; *Total Annual Hours:* 108.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on August 15, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 9, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–9478 Filed 6–15–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–194 and CMS–R–52]

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

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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 function; (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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Disproportionate Share Adjustment Procedures and Criteria and Supporting Regulations in 42 CFR 412.106; *Use:* A hospital's disproportionate share adjustment is determined by its fiscal intermediary (FI) using a combination of Medicare Part A and Supplemental Security Income data provided by CMS, and Medicaid data calculated from the hospital's cost report. The data provided through these calculations are then compared to the qualifying criteria located in 42 CFR 412.106 to determine the final adjustment. If these calculations, based on the Federal fiscal year, do not allow the hospital to qualify for a disproportionate share adjustment, the hospital may request that the calculations be performed using its cost reporting period; *Form Number:* CMS–R–194 (OMB#: 0938–0691); *Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 100; *Total Annual Responses:* 100; *Total Annual Hours:* 100.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services and Supporting Regulations Contained in 42 CFR 405.2100–405.2171; *Use:* The requirements associated with the Medicare and Medicaid Conditions for Coverage for Suppliers of ESRD Services fall into two categories: record keeping requirements and reporting requirements. With regard to the recordkeeping requirements, CMS uses these conditions for coverage to certify health care facilities that want to participate in the Medicare or Medicaid programs. These record keeping requirements are no different than other conditions for coverage in that they reflect comparable standards developed by industry organizations such as the Renal Physicians Association, American Society of Transplant Surgeons, and the National Association of Patients on Hemodialysis and Transplantation. With respect to reporting requirements, the information is needed to assess and ensure proper distribution and effective utilization of ESRD treatment resources while maintaining or improving quality of care. It is CMS's responsibility to closely monitor ESRD service utilization to prevent over-expansion of facilities

and resultant under-utilization; *Form Number:* CMS–R–52 (OMB#: 0938–0386); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profit and Federal government; *Number of Respondents:* 4,757; *Total Annual Responses:* 4,757; *Total Annual Hours:* 160,702.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503. Fax Number: (202) 395–6974.

Dated: June 9, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–9479 Filed 6–15–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0222]

Merck & Co., Inc., et al.; Withdrawal of Approval of 65 New Drug Applications and 52 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 65 new drug applications (NDAs) and 52 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective June 16, 2006.

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

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their requests, waived their opportunity for a hearing.

Application No.	Drug	Applicant
NDA 1–645	Vitamin B6 (pyridoxine hydrochloride (HCl))	Merck & Co., Inc., 770 Sumneytown Pike, P.O. Box 4, BLA–20, West Point, PA 19486–0004
NDA 5–521	Heparin Sodium Injection USP	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285
NDA 5–657	Tubocurarine Chloride Injection USP	Bristol-Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543–4500
NDA 5–794	Sultrin Triple Sulfa Cream and Triple Sulfa Tablets	Ortho-McNeil Pharmaceutical, Inc., 1000 U.S. Highway 202, P.O. Box 300, Raritan, NJ 08869–0602
NDA 6–012	Folvron (folic acid and iron)	Lederle Laboratories, 401 North Middleton Rd., Pearl River, NY 10965
NDA 7–149	Rubramin (cyanocobalamin) Tablets and Capsules	Bristol-Myers Squibb Co.
NDA 7–504	Acthar (corticotropin for injection)	Aventis Pharmaceuticals, Inc., 200 Crossing Blvd., BX 2–309E, Bridgewater, NJ 08807
NDA 7–794	Neothylline (dyphylline)	Teva Pharmaceuticals USA, 1090 Horsham Rd., P.O. Box 1090, North Wales, PA 19454
NDA 9–176	Cortril (hydrocortisone) Topical Ointment	Pfizer Global Pharmaceuticals, 235 East 42nd St., New York, NY 10017
NDA 10–028	Equanil (meprobamate) Tablets	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 10–093	Biphetamine (dextroamphetamine and amphetamine) Capsules	Celltech Pharmaceuticals, Inc., 755 Jefferson Rd., P.O. Box 31710, Rochester, NY 14603
NDA 10–513	Ketonil (amino acids and electrolytes)	Merck & Co., Inc.
NDA 10–787	Iron Dextran Injection	Aventis Pharmaceuticals, Inc.
NDA 10–799	Dimetane (brompheniramine maleate) Tablets and Extendtabs	Wyeth Consumer Healthcare, 5 Giralda Farms, Madison, NJ 07940
NDA 11–340	Cerumenex (triethanolamine polypeptide oleate-condensate), 10%	The Purdue Frederick Co., 1 Stamford Forum, Stamford, CT 06901–3431