I. Background

In the **Federal Register** of December 27, 2001 (66 FR 66910), FDA published a notice of availability for a draft guidance document entitled ''Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora.'' The agency gave interested persons until March 27, 2002, to comment on the draft guidance. FDA received several comments that were considered in the preparation of this guidance document. This guidance replaces former guidance #52 entitled ''Microbiological Testing of Antimicrobial Drug Residues in Food.'' A document entitled ''History and Scientific Issues Related to Guidance #52'' provides the scientific rationale for the revisions made (Docket No. 93D–0398).

CVM is aware that the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is currently drafting a related guideline and that this guidance may be superceded at a future date by the guideline published by VICH.

II. Paperwork Reduction Act of 1995

FDA is announcing that a collection of information entitled ''Guidance for Industry: Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. In the **Federal Register** of March 4, 2003 (68 FR 10253), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. The valid OMB control number for this information collection is 0910–0521. It expires on January 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

III. Significance of Guidance

This level 1 guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

V. Electronic Access

Persons with access to the Internet may obtain a copy of the guidance document entitled ''Guidance for Industry: Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora'' from FDA's CVM home page at *http://www.fda.gov/cvm*.

Dated: October 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3557 Filed 2–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for Ciloxan (ciprofloxacin ophthalmic), Brevibloc (esmolol), Flovent (fluticasone), Fludara (fludarabine), Fosamax (alendronate), Lotensin (benazepril), Malarone (atovaquone and proguanil), Xenical (orlistat), and Ocuflox (ofloxacin ophthalmic). The summaries are being made available consistent with section 9 of the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: The summaries are available for public examination between 9 a.m. and 4 p.m., Monday through Friday, in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the summaries to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT: Grace N. Carmouze, Center for Drug Evaluation and Research (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, *CarmouzeG@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for Ciloxan (ciprofloxacin ophthalmic), Brevibloc (esmolol), Flovent (fluticasone), Fludara (fludarabine), Fosamax (alendronate), Lotensin (benazepril), Malarone (atovaquone and proguanil), Xenical (orlistat), and Ocuflox (ofloxacin ophthalmic). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107–109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this

provision of the BPCA, FDA has posted on the Internet (*http://www.fda.gov/cder/pediatric/index.htm*) summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for Ciloxan (ciprofloxacin ophthalmic), Brevibloc (esmolol), Flovent (fluticasone), Fludara (fludarabine), Fosamax (alendronate), Lotensin (benazepril), Malarone (atovaquone and proguanil), Xenical (orlistat), and Ocuflox (ofloxacin ophthalmic). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/pediatric/index.htm*.

Dated: February 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3644 Filed 2–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Presidential Initiative Application Forms for Funding Opportunities—In Use Without Approval

The Consolidated Health Center Program is administered by the Health Resources and Services Administration's (HRSA) Bureau of Primary Health Care (BPHC). Grant funding opportunities are provided for Health Centers under the Presidential Initiative to expand health centers. These funding opportunities use the following applications: New Access Point Funding (NAP), Service Area Competition (SAC), the Expanded Medical Capacity (EMC) for Consolidated Health Centers and the Service Expansion (SE). These application forms are used by new and current Health Centers to apply for funding.

The five-year President's Initiative to Expand Health Centers will significantly impact 1,200 of the Nation's neediest communities by creating new health center sites. Additional emphasis will be given to improving and strengthening existing sites and expanding existing centers.

BPHC will assist in achieving the Initiative through the various funding opportunities under this Initiative. This year's funding increase supported the development of an additional 100 new access points and 88 significantly expanded access points. New access points will be established by Health Centers targeting the neediest communities using successful Center models. Expanded capacity will be targeted to communities where an existing Health Center's ability to provide care falls short of meeting the full need for services to uninsured and underserved populations. Funding will be provided to Health Centers to support the staff needed to serve a substantial increase in users.

Estimates of annualized reporting burden are as follows:

Type of application form	Number of respondents	Hours per response	Total burden hours
NAP	500	60	30,000
SAC	250	50	12,500
EMC	225	25	5,625
SE	450	25	11,250
Total	1,425	.....	59,375

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Desk Officer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 12, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–3647 Filed 2–18–04; 8:45 am]

BILLING CODE 4165–15–P

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) 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