approximately 2:30 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 10, 2004, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Beverly O'Neill at 301–827–7001, at least 7 days in advance of the meeting.

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

Dated: February 12, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–3645 Filed 2–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 17, 2004, from 1 p.m. to 5 p.m.

Location: Food and Drug Administration, 8800 Rockville Pike, Bldg. 29B, Conference Room C, Bethesda, MD. This meeting will be held by a telephone conference call. The public is welcome to attend the meeting at the previously mentioned location. A speaker telephone will be provided at the specified location for public participation in this meeting.

Contact Person: William Freas or Denise H. Royster, Food and Drug Administration, Center for Biologics Evaluations and Research (HFM–71), 1401 Rockville Pike, Rockville, MD, 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: This committee will discuss recommendations pertaining to the influenza virus vaccine formulation.

Procedure: On March 17, 2004, from 1 p.m. to 5 p.m., the meeting is open to the 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 March 11, 2004. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 11, 2004, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public as its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Denise H. Royster at least 7 days in advance of the meeting.

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

Dated: February 11, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04–3487 Filed 2–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1993D–0398]

Guidance for Industry: Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#52) entitled ''Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora.'' This guidance is a revision of the guidance document #52 entitled ''Microbiological Testing of Antimicrobial Drug Residues in Food,'' which was implemented in 1996. In this guidance, the agency recommends a pathway approach for assessing the microbiological safety of antimicrobial drug residues in food, rather than the approach described in the 1996 version of the guidance. The agency's decision to revise this guidance is based on new information available to the agency.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written comments on this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT: Haydee Fernandez, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6981, e-mail: *afernand@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

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