The estimate of the times required for record preparation and maintenance is based on agency communications with industry. Other information needed to finally calculate the total burden hours (i.e., number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from agency records and experience.

Dated: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–13215 Filed 6–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0483]

Agency Information Collection Activities; Announcement of OMB Approval; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Labeling Regulations'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 18, 2004 (69 FR 7643), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0381. The approval expires on May 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–13216 Filed 6–10–04; 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 Cipro (ciprofloxacin), Corlopam (fenoldopam), Glucovance (glyburide and metformin), Arava (leflunomide), Viracept (nelfinavir), Concerta (methylphenidate), Zemplar (paricalcitol), Zomig (zolmitriptan), and Ortho Tri-Cyclen (norgestimate and ethinyl estradiol). The summaries are being made available consistent with 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: 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 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 Cipro (ciprofloxacin), Corlopam (fenoldopam), Glucovance (glyburide and metformin), Arava (leflunomide), Viracept (nelfinavir), Concerta (methylphenidate), Zemplar (paricalcitol), Zomig (zolmitriptan), and Ortho Tri-Cyclen (norgestimate and ethinyl estradiol). 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 (21 U.S.C. 355a). Section 505A 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 Cipro (ciprofloxacin), Corlopam (fenoldopam), Glucovance (glyburide and metformin), Arava (leflunomide), Viracept (nelfinavir), Concerta (methylphenidate), Zemplar (paricalcitol), Zomig (zolmitriptan), and Ortho Tri-Cyclen (norgestimate and ethinyl estradiol). 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: June 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–13217 Filed 6–10–04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Environmental Planning Program

AGENCY: Department of the Homeland Security.

ACTION: Notice of proposed directive; request for comments.