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.


Jeffrey Shuren,
Assistant Commissioner for Policy.

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


Jeffrey Shuren,
Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Environmental Planning Program

AGENCY: Department of Homeland Security.

ACTION: Notice of proposed directive; request for comments.


Jeffrey Shuren,
Assistant Commissioner for Policy.

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