

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Item	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Total Hours					28,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on submissions received to date and registration and listing records for the affected devices, FDA estimates that there are 20 reproducers of SUDs that will need to submit validation data. In calendar year 2003, FDA estimates that there will be 5 new 510(k)s for reproducers of SUDs. Based on its experience with reviewing 510(k)s and discussions with reproducers, FDA estimates that it will take 40 hours per 510(k) to develop and submit the validation data. This results in a total burden of 4,000 for 2003. (In this estimate, FDA is only taking into account the burden related to validation data. The other collections of information related to the submission of information in a 510(k) have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910-0120).

In 2004, reproducers with previously exempt and cleared devices will need to submit their validation data by January 30, 2004, and July 30, 2004. For 2004, FDA estimates that the 20 manufacturers will submit an average of 20 510(k)s each for a total burden of 16,000 hours.

In 2005, FDA estimates that the 20 manufacturers will submit 10 new 510(k)s each. This will result in a total burden of 8,000.

Dated: July 1, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0285]

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 the medical

and clinical pharmacology reviews of pediatric studies submitted in supplements for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). 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: 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: Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD-950), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-7337, CrescenziT@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of the medical and clinical pharmacology reviews of pediatric studies conducted for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). 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 the medical and clinical pharmacology reviews of the pediatric studies submitted in supplements for Hycamtin (topotecan), Pulmicort (budesonide), Temodar (temozolomide), Effexor (venlafaxine), Ditropan (oxybutynin), Flonase (fluticasone), Allegra (fexofenadine), Duragesic (fentanyl), and Monopril (fosinopril). Copies are also available for public examination in the Division of Dockets Management or may be requested by mail (see **ADDRESSES**).

II. Electronic Access

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

Dated: June 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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