TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of survey	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Internet survey	3,240	1	3,240	.25	810
Total					810

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

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed in this document.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1522 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0032]

Referral of ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests for the Conduct of Pediatric Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the referral of ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests for the conduct of pediatric studies to the Foundation for the National Institutes of Health (the Foundation). FDA referred the ZINECARD (dexrazoxane) and RELPAX (eletriptan) Written Requests to the Foundation on August 29, 2005, and is publishing this notice of the referrals in accordance with the Best Pharmaceuticals for Children Act (BPCA).

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 1613, Silver Spring, MD 20993–0002, 301–796–2200, e-mail: *carmouzeg@cder.fda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with section 4 of the BPCA (Public Law 107–109), FDA is announcing the referral to the Foundation of the written requests for the conduct of pediatric studies for ZINECARD (dexrazoxane) and RELPAX (eletriptan). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the exclusivity incentive 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 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.

The BPCA established additional mechanisms for obtaining information on the safe and effective use of drugs in pediatric patients. Specifically, section 4 of the BPCA amends section 505A(d) of the act to create a referral process to obtain studies for drugs that have patent or exclusivity protection, but for which the sponsor has declined to conduct the pediatric studies in response to a written request by FDA. Under section 4 of the BPCA, if the Secretary of Health and Human Services (the Secretary) determines that there is a continuing need for the pediatric studies described in the written request and the sponsors of the products with patent or exclusivity protection have declined to conduct the studies, the Secretary shall refer the drug to the Foundation, established under section 499 of the Public Health Service Act (42 U.S.C. 290(b)), for the conduct of the pediatric studies described in the written request (21 U.S.C. 355a(d)(4)(B)(i)). In addition, the BPCA requires public notice of the name of the drug, name of the manufacturer, and indications to be studied under the referrals (21 U.S.C. 355a(d)(4)(B)(ii)).

In accordance with section 4 of the BPCA, FDA is announcing that on August 29, 2005, it referred to the Foundation the written requests for pediatric studies for ZINECARD (dexrazoxane) and RELPAX (eletriptan). On July 14, 2004, FDA issued a written request for pediatric studies to Pfizer, Inc., the holder of approved applications for RELPAX (eletriptan) that have market exclusivity. The studies described in the written request were for the acute treatment of migraines in adolescents. Pfizer, Inc., declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of RELPAX (eletriptan) in the pediatric population.

On June 17, 2004, FDA issued a written request for pediatric studies to Pfizer, Inc., the holder of approved applications for ZINECARD (dexrazoxane) that have market exclusivity. The studies described in the written request were for cardioprotection in children receiving doxorubicin therapy. Pfizer, Inc., declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of ZINECARD (dexrazoxane) in the pediatric population.

Dated: January 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1520 Filed 2–3–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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