

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

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

<sup>1</sup>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.*

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## 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](mailto: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.*

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## 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

quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Social Network Analysis of a Service System for Transition Aged Youth—New**

SAMHSA's, Center for Mental Health Services will seek information about the change in the network of social services in one community, Clark County Washington, as a result of a Center for Mental Health Services funded grant initiative, the Options Program. The Options program was one of 5 funded sites across the country. Each site received four years of funding to build comprehensive supports that help adolescents with serious emotional disturbance and their families make the difficult transition from adolescent to adult functioning through the age of 25.

This grant program, called the Partnerships for Youth Transition, aims to remediate some of the most difficult system barriers that interfere with transition system building by providing community leaders and advocates funding for direct services and infrastructure building, technical assistance to help shape the vision, and time to establish programs and interagency relationships. Since no single site in the country has ever successfully built a transition support system we do not know whether combining the resources of this grant, with the resources of the community are sufficient to make significant strides in transition system building. It is imperative to answer this question systematically and rigorously in order to guide future efforts.

There have been 110 agencies identified in Clark County that could potentially serve youth or young adults with serious mental, emotional and behavioral disorders. This study will

conduct network analysis by interviewing one key informant from each of these programs about their organization's professional relationship with other social services. The Social Network Questionnaire was previously developed for use in several studies in mental health and homeless services. Questions focus on aspects of professional relationship such as how often clients are referred to another agency and how often staff meet for client planning purposes with staff from another agency, as well as some background information about the agency and the quality of services offered. An additional 10 items focus on whether the program is following guidelines for exemplary practice with transition aged youth. Findings will be compared to data collected prior to program initiation.

The following table summarizes the estimated response burden for this project.

Respondent	Number of respondents	Responses/ respondent	Total responses	Hours per response	Total hour burden
Key informants from social services in Clark County .....	110	1	110	1.25	137.5

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7-1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 27, 2006.  
**Anna Marsh,**  
*Executive Officer, SAMHSA.*  
 [FR Doc. E6-1561 Filed 2-3-06; 8:45 am]  
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**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.  
**ACTION:** Notice and request for comments.

**SUMMARY:** The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revision of a

currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the National Urban Search and Rescue (US&R) grant program.

**SUPPLEMENTARY INFORMATION:** Section 303 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5144, authorizes the President of the United States to form emergency Support teams of Federal personnel to be deployed in an area affected by a major disaster or emergency. Under Section 403(a)(3)(B) of the Stafford Act provides that the President may authorize Federal agencies to perform work on public or private lands essential to save lives and protect property, including search and rescue and emergency medical care, and other essential needs. FEMA established the National Urban Search and Rescue Response System (US&R) under these authorities. The President amended E.O. 121448 to transfer the FEMA Director's delegated authority to the Secretary of Homeland Security.

**Collection of Information**

*Title:* National Urban Search and Rescue Program Agreement, Application, Reporting, and Audit Requirement.

*Type of Information Collection:* Revision of a currently approved collection.

*OMB Number:* 1660-0073.  
*Form Numbers:* None.  
*Abstract:* The information collection activity is the collection of financial, program and administrative information for US&R Sponsoring Organizations relating to preparedness and response grant awards. This information includes a narrative statement that FEMA uses to evaluate a grantee's proposed use of funds, progress reports to monitor overall progress on managing FEMA grant program, extension or change requests used to consider changing or extending the time or the performance period of the preparedness or response cooperative agreement and a memorandum of agreement between DHS/FEMA and the Sponsoring Organizations of US&R task forces as described below.

*Narrative Statement:* FEMA uses narrative statements to evaluate a grantee's proposed use of funds. Examples of information a grantee needs to provide FEMA for preparedness and response cooperative agreements are a description of the types of eligible activities the grantee will undertake, a plan for expending and monitoring funds, and an estimate of the percentage or amount of funds the grantee will pass through to sub-grantees. Sponsoring