As explained in detail in the guidance, there have been repeated instances of DEG poisoning that have led to the development of this guidance. Between 1990 and 1998, DEG poisoning has been reported in Haiti, Argentina, Bangladesh, India, and Nigeria. More recently, in October 2006, there were cases of illness and death in Panama due to DEG poisoning.

The cases involving DEG contamination reveal the following similarities:

- The pharmaceutical manufacturers did not perform full identity testing on the glycerin raw material, including tests to quantify the amount of DEG present and to verify the purity of the glycerin received.
- The pharmaceutical manufacturers of the contaminated products relied on the certificate of analysis (COA) provided by the supplier.
- The origin of the product was not easily apparent from the COA.

FDA has no reason to believe that the U.S. supply of glycerin is affected at the present time. However, because of the serious nature of this potentially fatal problem and the global nature of the pharmaceutical supply chain, FDA is emphasizing in this guidance the importance of testing glycerin for DEG.

We are issuing this level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The agency is not seeking comment prior to implementing this guidance because of the potential for a serious public health impact if DEG-contaminated glycerin were to enter the domestic market. The guidance represents the agency's current thinking on this issue. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 16, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–8389 Filed 5–1–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: Bureau of Primary Health Care (BPHC) Uniform Data System (OMB No. 0915–0193)—Extension for 2007 UDS Data Collection

The Uniform Data System (UDS) contains the annual reporting requirements for the cluster of primary care grantees funded by HRSA. The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Public Housing Primary Care, and other grantees under Section 330. The authorizing statute is Section 330 of the Public Health Service Act, as amended.

HRSA collects data in the UDS which is used to ensure compliance with legislative mandates and to report to Congress and policy makers on program accomplishments. To meet these objectives, HRSA requires a core set of data collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Universal Report	1,055	1	1,055	28	29,540
Grant Report	145	1	145	18	2,610
Total	1,055	.....	1,100	.....	32,150

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Karen Matsuoka, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 25, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7–8379 Filed 5–1–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.