

Dated: April 19, 2007.

Daniel C. Schneider,
Acting Assistant Secretary for Children and Families.

[FR Doc. E7-8318 Filed 5-1-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions and Delegation of Authority

Notice is hereby given that I have delegated to the Principal Deputy Assistant Secretary, Deputy Assistant Secretaries, Program Directors, Program Commissioners, Deputy Director/Commissioner, Office of Child Support Enforcement, and Staff Office Directors the following authority vested in me by the Secretary of Health and Human Services in the memorandum dated August 20, 1991, Delegations of Authority for Social Security Act Programs; 31 U.S.C. 1535; and HHS General Administrative Manual, Chapter 8-77.

(a) Authorities Delegated.

1. Authority to administer approved cooperative research experimental, pilot or demonstration projects under the provisions of sections 1110 and 1115 of the Social Security Act.

2. Authority to approve interagency agreements to procure, provide or exchange services, supplies or equipment.

(b) Limitations.

1. The authority listed in #1 above shall be exercised under the condition that projects may be administered by the Office of Planning, Research and Evaluation (OPRE), by the program/staff office or jointly by OPRE with the program/staff office.

2. Where all or any part of an experimental, pilot, research or demonstration project is wholly financed with Federal funds made available under sections 455(e), 1110 or 1115 of the Social Security Act, without any State, local or other non-Federal financial participation, that project must be approved by the Secretary of Health and Human Services.

3. This delegation of authority does not include the authority to approve/disapprove projects under sections 1110 or 1115 of the Social Security Act or approve/disapprove waivers of State Plan requirements or costs that would not otherwise be included as expenditures under the provisions of section 1115(a)(1) and (2) of the Social Security Act.

4. The authority to approve interagency agreements to procure, provide, or exchange services, supplies, or equipment requires the concurrence of the ACF Chief Financial Officer if it exceeds \$250,000 (including amendments) within a fiscal year or if it requires the signature of the Assistant Secretary, ACF, or the Secretary of HHS.

(c) Effect on Existing Delegations.

As related to this delegation of authority, this delegation supersedes all previous delegations of authority involving the administration of the cross-program authorities delegated herein.

(d) Effective Date.

This delegation is effective upon the date of signature.

I hereby ratify and affirm any actions taken by the Principal Deputy Assistant Secretary, Deputy Assistant Secretaries, Program Directors, Program Commissioners, Deputy Director/Commissioner, Office of Child Support Enforcement, and Staff Office Directors, which involved the exercise of the authority delegated herein prior to the effective date of this delegation.

Dated: April 19, 2007.

Daniel C. Schneider,
Acting Assistant Secretary for Children and Families.

[FR Doc. E7-8319 Filed 5-1-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0135]

Guidance for Industry on Testing of Glycerin for Diethylene Glycol; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, avoid the use of glycerin that is contaminated with diethylene glycol (DEG) and prevent incidents of DEG poisoning.

DATES: Submit written or electronic comments on the guidance by July 31, 2007. General comments on agency

guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Monica Caphart, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-9047.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance explains that the agency recommends that certain analytical testing procedures be performed on glycerin to avoid the use of DEG-contaminated product. Specifically, the agency is recommending that all lots of glycerin received by a pharmaceutical manufacturing facility undergo identity testing that includes a test for DEG content. DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1 percent, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. Repackers, pharmacy compounders, and others who distribute and prepare glycerin for use in drug products should test glycerin that is used, sold for use, or intended for use in drug products. This recommendation also applies to bulk or repackaged glycerin intended as an excipient or other component for a drug. In addition, pharmacies that purchase glycerin for use in compounding drug products should either test the glycerin or ensure that such testing was properly done by a reliable supplier.

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]

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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]
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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.