

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 [*insert date 90 days after date of publication in the Federal Register*]. 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.

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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. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S